UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

IN RE APPLICATION OF ORTHOGEN :

INTERNATIONAL GMBH,

Case No. 1:24-mc-504

Petitioner,

for an order pursuant to 28 U.S.C. § 1782 to conduct discovery for use in a foreign proceeding.

-----x

HIPAA QUALIFIED PROTECTIVE ORDER AND ORDER TO DISCLOSE PROTECTED HEALTH INFORMATION

This matter comes before the Court on Petitioner Orthogen International GmbH's ("Orthogen") request for entry of a HIPAA Qualified Protective Order and Order to Disclose Protected Health Information.

Orthogen has filed a petition pursuant to 28 U.S.C. § 1782 (the "1782 Petition") with this Court for an Order authorizing Orthogen to serve subpoenas (the "Subpoenas") on Judith Capla and Tomas Capla (the "Respondents") for documents and testimony (the "Discovery"). As set forth in the 1782 Petition, the Discovery is sought by Orthogen for use in connection with a contemplated foreign proceeding in Germany (the "Contemplated German Proceeding").

The Discovery produced by the Respondents in response to the Subpoenas may contain Protected Health Information ("PHI"). Accordingly, the Court issues this Order in accordance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations promulgated thereunder, including specifically 45 C.F.R. § 164.512(e)(1)(ii)(B) and 164.512(e)(1)(v), to enable the production by the Respondents of, and limit the use or disclosure of, any PHI.

As used herein, PHI shall have the same definition as set forth in 45 C.F.R. § 160.103.

- 1. The Respondents, Orthogen, and the anticipated defendants to the Contemplated German Proceeding (specifically, Dr. Douglas Schottenstein and Edward Capla), and each of their legal counsel (collectively, "Parties"), are hereby authorized through discovery to receive, subpoena, and transmit PHI, to the extent that such information is otherwise discoverable pursuant to the Subpoenas and not objectionable, subject to all conditions outlined herein. Pursuant to this Order, all Parties are:
 - a. prohibited from using or disclosing PHI for any purpose other than this matter, the
 Contemplated German Proceeding, or other proceedings brought pursuant to 28
 U.S.C. § 1782 in connection with the Contemplated German Proceeding; and
 - required to securely destroy all copies of PHI or to return them to the disclosing party within 30 days of the conclusion of this matter or the Contemplated German Proceeding, whichever occurs last, including any final appeals therefrom.
- 2. <u>Subpoenas</u>. Based upon this HIPAA Qualified Protective Order and commencing immediately from the date of this Order, the Respondents are hereby AUTHORIZED to use or disclose PHI in response to the Subpoenas served by Orthogen in this matter.
- 3. <u>Depositions</u>. In addition to the foregoing, pursuant to 45 C.F.R. § 164.512(e)(1)(i) and for purposes of HIPAA compliance, each deponent duly noticed for deposition in this matter is AUTHORIZED to use or to disclose to the attorneys, agents, employees, and designees of each Party in this matter or the Contemplated German Proceeding PHI that is responsive to deposition questions or the Subpoenas at such duly-noticed deposition.
- 4. <u>Judicial Proceedings</u>. In addition to the foregoing, pursuant to 45 C.F.R. §

 164.512(e)(1)(i) and for purposes of compliance with HIPAA, all Parties are hereby

 AUTHORIZED to use and disclose the PHI disclosed in this matter for purposes of any judicial

proceeding related to this matter, the Contemplated German Proceeding, or another proceeding brought pursuant to 28 US.C. § 1782 in connection with the Contemplated German Proceeding. If any party wishes to file PHI with a court, it must be submitted with a motion for filing under seal or comparable protection. However, any party may file a pleading or document with a court that describes, summarizes, quotes, or contains PHI, as long as that party omits or redacts the identifying information of the person to whom the PHI pertains. Any party may use documents containing PHI at trial or an evidentiary hearing, including but not limited to introducing them into evidence and asking a witness about their contents. If a party moves a document containing PHI into evidence or otherwise wants it to be part of the record, the relevant court may determine how to handle such documents.

- 5. The Parties and their attorneys in this matter, the Contemplated German Proceeding, or another proceeding brought pursuant to 28 U.S.C. § 1782 in connection with the Contemplated German Proceeding shall be permitted to use PHI in any manner reasonably connected with any such proceeding, including, but not limited to, disclosure to the parties and their attorneys, experts, consultants, any court and court personnel, outside vendors or service providers, and other persons and entities involved in any such proceeding.
- 6. Any person or entity involved in this matter, the Contemplated German Proceeding, or another proceeding brought pursuant to 28 U.S.C. § 1782 in connection with the Contemplated German Proceeding that is not a party to this matter to whom the sharing or disclosure of PHI occurs must, prior to receiving the PHI, sign the Acknowledgement attached hereto as Exhibit A. Counsel providing access to PHI shall retain copies of the executed Acknowledgement(s) and provide them to another party as requested.
 - 7. Nothing in this Order authorizes counsel to obtain medical records or information

through means other than formal discovery requests, subpoenas, depositions, patient authorizations, or other lawful process.

8. The provisions of this Order shall not terminate at the conclusion of this matter, the Contemplated German Proceeding, or any other related proceeding. This Order shall remain in full force and effect and each person or entity subject to this Order shall continue to be subject to the jurisdiction of the United States District Court for the Southern District of New York, for the purposes of enforcement of the terms of this Order.

SO ORDERED:

HON. VERNON S. BRODERICK UNITED STATES DISTRICT JUDGE

Date: April 30, 2025

EXHIBIT A

SOUTHERN DISTRICT OF NEW YORK	- X	
IN RE APPLICATION OF ORTHOGEN INTERNATIONAL GMBH,	: :	Case No.
Petitioner,	: :	
for an order pursuant to 28 U.S.C. § 1782 to conduct discovery for use in a foreign proceeding.	: : : : : : : : : : : : : : : : : : : :	
	- X	

UNITED STATES DISTRICT COURT

I further agree that I shall not disclose to others, except in accord with the Order, any PHI, in any form whatsoever, and that such PHI may be used only for the purposes authorized by the Order.

I further agree to return all copies of any documents or information containing PHI that I have received to counsel who provided them to me upon completion of the purpose for which they were provided and no later than the conclusion of the Contemplated German Proceeding referenced in the Order. I further agree and attest to my understanding that my obligation to honor the confidentiality of such PHI will continue even after this matter, the Contemplated

German Proceeding, and any other related proceeding concludes. I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Southern District of New York, for the purposes of any proceedings relating to enforcement of the Order, even if such enforcement proceedings occur after termination of this matter, the Contemplated German Proceeding, and any other related proceeding. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Acknowledgement.

Date:			
Printed Name:			
Signature:			